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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/099,048	06/17/1998	LAURETTE NACAMULLI	KM39091	4803

7590 03/26/2002

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EXAMINER	
CEPERLEY, MARY	
ART UNIT	PAPER NUMBER
1641	15

DATE MAILED: 03/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/099,048	HAYES ET AL.	
	Examiner	Art Unit	
	Mary (Molly) E. Ceperley	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-93 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) 1-36 is/are allowed.

6)☒ Claim(s) 37-51 and 53-93 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2) The original patent, or an affidavit or declaration as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed. See 37 CFR 1.178. In their October 25, 2001 response, applicants state that the original patent or the required affidavit or declaration will be submitted before this reissue application is allowed.

3) Although specific claims are cited in the rejections below, these rejections are also applicable to all other claims in which the noted problems/language occur.

4) Claims 37-51, 53-56 and 76-93 are rejected under 35 USC 112, first paragraph, as not corresponding with the enabling written description of the invention as it is set forth in the specification and as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, i.e. as containing new matter, for the following reasons.

a) Newly amended claim 37 has been amended to include the language "at least one reactant is converted to *one or more products*" and a final step of "*calculating* the time course of the reaction". Applicants have provided no discussion of where these new limitations are supported in the originally filed specification. There appears to be no description in the originally filed specification of either the "one or more products" and their exact composition or of what is involved in the "calculating" step.

b) There appears to be no description in the originally filed specification to support the method of newly presented claim 76. Applicants have provided no discussion of where the method of claim 76 is supported in the originally filed specification. Additionally, in the absence of the recitation of any reactants, the method of claim 76 would encompass a method of measuring **the time course f electrochemiluminescence decay of the lumin ph re *per se***, which is exposed to pulsed electrical

energy, i.e., the ECL decay of the luminophore would be the "reaction". The originally filed specification does not support such a method.

5) Claims 37-51, 53-56 and 76-93 are rejected under 35 USC 112, second paragraph, as being confusing, indefinite and/or incomplete for the following reasons.

a) In claim 37, it is unclear what is meant by the term "one or more products" and what steps are involved in the "calculating" step.

b) Claim 76 is indefinite and incomplete in failing to define the "reaction" to be measured. No reactants are specified.

6) The specification is again objected to under 37 CFR 1.71 and claims 37-51 and 53-93 are rejected under 35 USC 112, first paragraph, for the reasons stated in paragraphs 5. and 6. of the August 14, 2000 Office action and maintained in paragraphs 3. and 6. of the April 25, 2001 Office action.

Applicants' arguments filed October 25, 2001 have been fully considered but they are not persuasive for the following reasons.

a) The examiner does not agree with applicants' statement at page 10, fourth paragraph of the Remarks that the claims at issue are no broader than the broadest description present in the specification. The broadest ***enabling written*** description of the invention appears at col. 2, lines 21-65 of the specification. Applicants choose to selectively ignore the requirements stated in this section of the specification. For example, lines 27 and 28 state that "the reagents employed in the reaction, therefore, ***will include*** a **reaction partner** which reacts with the **reactant**...". Lines 32-34 state that "the method of the invention ***also requires*** the modulation and measurement of the ECL intensity of the biomolecular reaction and the demodulation of the intensity measurement".

b) Applicants' argument at page 11 of the Remarks regarding "undue experimentation" is misplaced since the examiner has not argued that "undue experimentation" would be required. Rather,

the examiner's position is that the broad generic concept of claims 37-51 and 53-93 is not supported by an enabling written description in the specification and that the broadest enabling written description of the invention is set forth at col. 2, lines 36-65 of the specification wherein the specifics of the required method steps are clearly delineated.

7) Claims 37-51 and 53-93 are again rejected under 35 USC 112, second paragraph for the reasons of record as stated in paragraphs 4. and 5. of the April 25, 2001 Office action and in paragraph 8. of the August 14, 2000 Office action.

The second paragraph of 35 USC 112, requires that the claims "particularly point out and distinctly claim the subject matter which the applicant regards as his invention". Although applicants argue at page 14 of the Remarks that they are entitled to determine what they "regard as their invention", the claimed subject matter which they "regard as their invention" must additionally correspond to the enabling written description of the invention as it is set forth in the specification and the claims must particularly point out and distinctly claim that invention. The claims at issue omit the steps recited in instant claim 1 which are clearly required to practice the invention as it is described at col. 2, lines 36-65 of the specification. The examiner's position as set forth in paragraphs 5. a)-c) of the last Office action is maintained for the reasons stated therein. Although the examiner agrees with applicants' statement that the claims must be read in light of the specification, the examiner and applicants do not agree on what the enabling written description of the specification establishes as the "invention". See paragraph ***6)*** above.

8) Claims 37-51 and 53-93 are rejected under 35 USC 103(a) as being obvious over each of ***(1)*** Martin et al, Bard et al or Shibue et al taken in combination with each of ***(2)*** Karlsson et al, Sieber or Freundlich et al for the reasons of record (paragraph 8. of the last Office action).

Applicants' arguments have been fully considered but they are not persuasive. Applicants have not addressed the rejection as it relates to the ***combination*** of references ***(1)*** and ***(2)*** and the

reasoning set forth in paragraph 8. of the last Office action. Applicants' arguments regarding references ***(1)*** are directed to a discussion of how these references do not address the measurement of the *time course* of an ECL reaction. This point has already been acknowledged by the examiner in the last Office action in paragraph 8., second subparagraph, i.e. "these references describe standard determinations of ECL intensity versus analyte concentration...but do not specifically describe monitoring the time course of the reaction". Further, applicants argue that references ***(2)*** are directed to non-ECL methods but do not acknowledge or address the **reason** for which these references are applied, i.e., to "establish that it is well known in the art to monitor the time course (i.e. kinetics) of both antigen-antibody and enzyme-enzyme substrate reactions using conventional analytical methodology". Contrary to applicants' statement at page 21, second paragraph of the Remarks, the motivation to combine references ***(1)*** and ***(2)*** is set forth in the second paragraph of page 6 of the last Office action. Applicants have not established criticality for the use of a conventional ECL method (as described in references ***(1)***) for determining the time course of a reaction versus the use of other conventional analytical methods which are known for monitoring the time course of a reaction (references ***(2)***). Although applicants present a discussion at page 18, first paragraph of the Remarks indicating that the claimed ECL method achieves "surprising and unexpected results", there is no description in the specification to support such an assertion.

9) Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing

date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. (Molly) Ceperley whose telephone number is (703) 308-4239. The examiner can normally be reached from 8 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-7230.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

March 22, 2002

Mary E. Ceperley
Primary Examiner
Art Unit 1641